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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,112	01/14/2002	William H Cork	F-5629 (CORK 100 US)	2485

7590 01/22/2004

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EXAMINER

CECIL, TERRY K

ART UNIT	PAPER NUMBER
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1723

DATE MAILED: 01/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

AS

Office Action Summary	Application No.	Applicant(s)	
	10/031,112	CORK ET AL.	
	Examiner	Art Unit	
	Mr. Terry K. Cecil	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>10/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

It is noted that applicant has canceled the nonelected claims.

Claim Rejections - 35 USC § 102

Since the added limitation fails to further structurally limit the elected apparatus, the 102 rejection of the prior office action is maintained.

Claim Rejections - 35 USC § 103

Since the added limitation fails to further structurally limit the elected apparatus, the 103 rejection of the prior office action is maintained.

IDS

1. The IDS filed 10-30-2003 has been considered by the examiner. An initialed copy is included herewith. However, it is noted that several references have been crossed out since they have already been considered—as indicated in a previous IDS or form-1449.

Response to Arguments

2. Applicant's arguments filed 12-11-03 have been fully considered but they are not persuasive because of the following reasons:

- Applicant argues that his invention is an *in vivo* system (positioned within a living organism). However, the examiner points out that such has not been claimed and further contends that applicant's invention is geared to an *in vitro* system since the elements thereof are positioned outside the human body, as shown in his drawings (e.g. figure 3).
- In order to distinguish from Mian, applicant has added the phrase "wherein said first fluid flow path is in continuing direct communication" with a vascular system of the human subject. However, the examiner contends such a limitation is more conducive to a method claim and fails to further limit the structure of the apparatus. The limitation is geared more to the way in which the apparatus is used. In Mian, blood from the lanced fingered is drawn into the first flow path by capillary action. As long as the finger is in the lancing position the "continuous" direct contact is effected. Did applicant intend to claim the structure of venous and arterial sets (including tubing and needles) which would allow blood to continuously flow to the system and back to the patient as in his specification? Such structure has not been claimed and is not part of the elected invention. Such structure is also known in the art, e.g. prince. It is also pointed out that the added limitation of "continuing and direct communication" does not require the flow path of the system to be in contact with the human vascular system for any definite amount of time—as admitted by the applicant (page 6 of 8, lines 6-8). The added limitation fails to further structurally define the claimed apparatus.

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- Concerning the rejection of Prince in view of Bullister, applicant argues that the MEMs sensor is not “for sensing a selected characteristic of the fluid within the flow path” since the MEMs sensor of the prior art is for transport characteristics, such as flow rate or pressure. However, the examiner points out that flow rate and pressure *are* characteristics of the fluid and meets the limitation of claim. A sensor capable of detecting e.g. cell count or blood type, as argued by the applicant has not been claimed in claim 34. It is also pointed out that even applicant’s abstract indicates that flow rate and pressure are possible fluid characteristics determined by the sensor.
- Before amending the claims in a continuing application, the applicant should consider the obviousness of combining the system of Prince (which desires information such as cell identification) with a MEMs sensor [admitted by the applicant to be already conceived (known), see the last paragraph of page 7] or by combining Prince with the MEMs sensor of Mian.

Conclusion

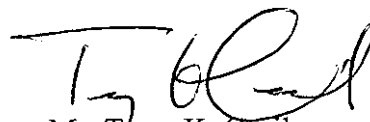
3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the

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advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

4. Contact Information:

- Examiner Mr. Terry K. Cecil can be reached at (571) 272-1138 at the Carlisle campus in Alexandria, Virginia for any inquiries concerning this communication or earlier communications from the examiner. Note that the examiner is on the increased flextime schedule but can normally be found in the office during the hours of 8:30a to 4:30p, on at least four days during the week M-F.
- Wanda Walker, the examiner's supervisor, can be reached at (571) 272-1151 if attempts to reach the examiner are unsuccessful.
- The Fax number for this art unit for official faxes is 703-872-9306.



Mr. Terry K. Cecil
Primary Examiner
Art Unit 1723

TKC
January 15, 2004